CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-720/S-011

CHEMISTRY REVIEW(S)

NDA SUPPLEMENT REVIEW

CHEMIST'S REVIEW	1. **ORGANIZATION** DAIDP (HFD-520)	2. **NDA NUMBER** 50-720

3. **NAME & ADDRESS OF APPLICANT**
Smithkline Beehcam Pharmaceutics
1250 South Collegeville Road,
P.O. Box 5089, Collegeville
PA 19426-0989

4. **AF NUMBER**

5. **SUPPLEMENT(s)**

NUMBER(s)	**DATE(s)**
[redacted]	6/30/00

6. **NAME OF DRUG**
Augmentin Tablet

7. **NONPROPRIETARY NAME**
Amoxicillin/Clavulanate Potassium tablet

8. **SUPPLEMENT(s) PROVIDES FOR:**
An additional source of amoxicillin trihydrate source manufactured by [redacted]

9. **AMENDMENTS AND OTHER (REPORTS, etc.) DATES**

10. **PHARMACOLOGICAL CATEGORY**
Anti-bacterial

11. **HOW DISPENSED**
X
Rx OTC

12. **RELATED IND/NDA/DMF(s)**
[redacted]

13. **DOSAGE FORM(s)**
Tablet

14. **POTENCY(ies)**
875 mg

15. **CHEMICAL NAME AND STRUCTURE**
Amoxicillin Trihydrate $C_{15}H_{19}N_3O_5S.3H_2O$ & Clavulanate Potassium $C_8H_8KNO_5$
(2S,5R,6R)-6-[(R)-(-)-2-amino-2-(p-hydroxyphenyl)acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate.
Potassium (Z)-(2R,5R)-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]-heptane-2-carboxylate

16. **RECORDS AND REPORTS**

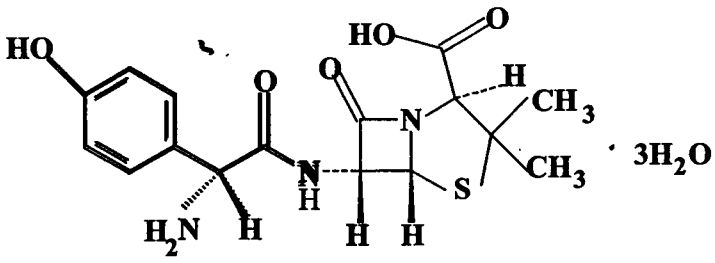
	Yes	No
CURRENT	X	
REVIEWED	X	

17. **COMMENTS** Please refer to NDA 50-725/SCM010 dated 5/2/01, bundled review.

18. **CONCLUSIONS AND RECOMMENDATIONS**
Recommend approval letter to issue for this supplement.

cc: Orig: NDA 50-720
HFD-520
HFD-520/Osterberg
HFD-520/Yu
HFD-520/Gavrilovich
HFD-520/Makhene
HFD-520/ Samanta
HFD-520/DKatague:R/D initialed

NAME	**REVIEWER SIGNATURE**	**DATE COMPLETED**
Andrew Yu PhD		2-May-2001



20. Components and Composition
n/a

21. Facilities and Personnel
n/a

22. Synthesis Adequate
amoxicillin trihydate manufactured by [redacted] The DMF was transferred from [redacted] Changes to the supplement occurred in 2/14/96 and 5/2/97 and were both reviewed and approved. The AADA was converted to DMF in 1998 as a result of FDAMA act. [redacted]

[redacted]

23. Raw Material Controls n/a
    a. New Drug Substance
    b. Other Ingredients

24. Other Firm(s)
    n/a

25. Manufacturing and Processing

APPEARS THIS WAY
ON ORIGINAL

26. Container/Closure
    n/a

27. Packaging and Labeling
    n/a

28. Laboratory Controls (In-process and Finished Dosage Form) n/a

29. Stability Adequate

Three months long term stability data were reported for three batches of Augmentin product produced with the alternate ———— The results are satisfactory, the level of degradation are generally equal to or less than that produced from the NDA approved drug source. Long term stability results will be reported/updated in annual reports.

30. Control Numbers
    n/a

31. Samples and Results
    n/a

32. Labeling
33. **Establishment Inspection** Adequate
Please refer to NDA 50-725/SCM010 dated 5/2/01 for detail, Bundled supplements:
50720/S011/Augmentin BID tablet
50564/S039/Augmentin TID tablet
50726/S009/Augmentin chewable tablet
50725/S010/Augmentin BID oral

34. Recalls
n/a

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Andy Yu
5/2/01 12:24:36 PM
CHEMIST

David Katague
5/2/01 12:58:10 PM
CHEMIST